Optimal Endovascular Treatment of Aorto-Iliac Occlusive Disease: Proper Stent or Stentgraft Selection and Technical Tips

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Disclosures
- WL Gore: Speaker and Consultant
- Principal Investigator in the US IDE Study evaluating the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis

Publication Highlights
- Complex long segment lesions can be easily treated with iliac stenting
- TASC classification does not alter outcome significantly
- In TASC II D lesions CS showed improved outcomes, otherwise BMS and CS equivalent
- COBEST Trial showed enduring benefits of CS over BMS at 5 years


Impact of stent-graft studies on treatment for Complex IOD
- Multiple consensus and practice guidelines now generally endorse an endovascular-first strategy for TASC II C & D IOD lesions in experienced endovascular centers
- Stentgrafts offer proven and theoretical advantages for complex lesions
  - Exclude plaque and prevent in-stent neointimal hyperplasia
  - Decrease risk of complications stemming from distal embolization, perforation, rupture, or dissection
  - Promote hemodynamic flow via a new flow lumen

Self-expanding vs balloon-expanding peripheral stents; attribute/performance comparisons

Self-Expanding Stent
- Shape memory alloys (e.g., nitinol)
- Deployed via release of constraining mechanism

Balloon Expandable Stent
- Ductile metal alloys (e.g., stainless steel)
- Deployed via angioplasty (PTA) balloon inflation

Generalized comparison of attributes

<table>
<thead>
<tr>
<th>Attribute</th>
<th>SX</th>
<th>BX</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial strength / recoil resistance</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Trackability, implanted conformability</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Diameter adjustment (flare/flare)</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Deployment accuracy</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Compression recovery</td>
<td>+</td>
<td>-</td>
</tr>
</tbody>
</table>

When is a BX stent desired for IOD treatment?
- Highly calcified/non-compliant lesion
- Tapered vessel
- Distal lesion

A BX stent-graft engineered specifically for IOD
- Flexibility (on catheter and implanted)
- Trackability through tortuous vessels
- Conformability once implanted
- Ability to withstand longitudinal compression (e.g., iliac)
- Accurate placement (minimal foreshortening)
- Improved stent retention on delivery system (tracking and deploying)
- Avoid “endotrauma”, stent embolization, retrieval
**Ideal characteristics of an Iliac Stent**

- Wide range of sizing and oversizing
- Good visibility during implantation
- Respects the angulation of the vessel
- Durable and flexible after flaring, during the cardiac cycles, the diaphragmatic motion
- High radial forces and resistance to compression (calcified vessel)
- Stent retention during navigation
- High trackability of the delivery system

**Unique technology and performance VBX**

- Independent stainless steel rings
- Independent rings for flexibility and conformability
- Minimizes foreshortening
- Provides high radial strength
- Stent retention during navigation
- High trackability of the delivery system
- High radial forces and resistance to compression (calcified vessel)
- Stent retention during navigation
- High trackability of the delivery system

**VBX FLEX: Eligibility criteria more reflective of real-world patients**

- Patient population and treatment approach closely aligned with current standard of care
- Allowed for more challenging patient population (anatomy and disease) than that seen in historical iliac stent studies - eligibility criteria permitted (without limitation) patients with:
  - Tortuous iliacs
  - Severe lesion calcification
  - Total occlusions
  - Need for direct stenting (pre-dilatation not required)
  - Kissing stent treatment at the aortic bifurcation

**VBX FLEX Study estimates of secondary endpoints**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>1 Week</th>
<th>3 Months</th>
<th>6 Months</th>
<th>12 Months</th>
<th>24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary</td>
<td>90.0% (98/109)</td>
<td>96.7% (106/110)</td>
<td>96.3% (112/115)</td>
<td>94.0% (114/121)</td>
<td>94.5% (120/126)</td>
</tr>
<tr>
<td>Secondary</td>
<td>90.0% (98/109)</td>
<td>96.7% (106/110)</td>
<td>96.3% (112/115)</td>
<td>94.0% (114/121)</td>
<td>94.5% (120/126)</td>
</tr>
</tbody>
</table>

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**VCORE (iCast)**

- Prospective, multicenter RCT comparing iCast to BMS
- Primary endpoint: Binary restenosis (defined by ≥50% reduction in lumen diameter) and freedom from stent occlusion at 18 months
- Anatomic criteria:
  - Occluded superficial and profunda femoral arteries excluded
  - Evidence of TASC B, C, or D lesions, excluded TASC A
  - Hemodynamically significant dissections and recurrent stenosis after angioplasty

**BOLSTER (Lifestream)**

- Prospective, multicenter Single Arm
- Primary endpoint: Composite of device- or procedure-related death or myocardial infarction (MI) through 30 days; or target lesion revascularization (TLR), major amputation of the target limb (ie, at or above the ankle), or re-stenosis through 9 months
- Anatomic criteria:
  - Severe calcification of the target lesion(s) preventing predilation excluded
  - Single, bilateral, or multiple lesions >50% de novo or restenotic (nonstented) in the common or external iliac artery (investigator’s visual estimate)
  - A lesion that could be crossed with a guidewire and predilated with a PTA balloon; chronic total occlusion catheters or reentry devices were allowed
  - Excluded a preexisting aneurysm, perforation, or dissection of the target iliac
  - Excluded target lesion located in the distal external iliac artery
  - Excluded target lesion involving the origin of the internal iliac artery, unless the internal iliac artery is already occluded

**VTA**

- VTA = external iliac artery; fTLR = freedom from target lesion revascularization; fCD-TLR = freedom from clinically driven TLR; TASC II C and D = TransAtlantic Inter-Society Consensus II (TASC II) C and D; NE = not evaluable.

* Kaplan-Meier Estimates of Secondary Endpoints Evaluated on a Per-Patient Basis
** EIA evaluated on a per-lesion basis

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1. Holden A. Comparison of four balloon expandable covered stents for the treatment of aorto-iliac occlusive lesions: which, where and when? Presented at the 45th Annual Symposium on Vascular and Endovascular Issues, Techniques, Horizons (VEITHsymposium); November 13-17, 2018; New York, N Y.
Change in Rutherford category

<table>
<thead>
<tr>
<th>Change in Rutherford category</th>
<th>30 days</th>
<th>2 months</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved</td>
<td>34.80%</td>
<td>34.00%</td>
<td>34.60%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>54.40%</td>
<td>54.00%</td>
<td>54.30%</td>
</tr>
<tr>
<td>Worsened</td>
<td>10.80%</td>
<td>12.00%</td>
<td>11.10%</td>
</tr>
</tbody>
</table>

Resting ABI

<table>
<thead>
<tr>
<th>ABI score</th>
<th>Pre-op</th>
<th>9 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI score</td>
<td>0.77 (0.37)</td>
<td>0.71 (0.11)</td>
<td>0.56 (0.38)</td>
</tr>
</tbody>
</table>

**Treatment Pearls**

- CTA improves preoperative planning
- Calcified lesions, particularly at the iliac ostium, are best treated with balloon-expandable stents.
- SESs are generally more appropriate for EIAs, although VBX has shown itself just as effective
- Covered stents provide greater durability and safety compared to bare-metal stents.
- Optimizing outflow with a CFA endarterectomy using a hybrid technique can be critical to preserve long-term patency
- Use the CERAB technique when the lateral wall of the distal aorta has plaque to preserve iliac cross-over and maximize laminar flow.

**Conclusions**

- Proven efficacy and benefits of covered stents for the treatment of iliac occlusive disease
- Multiple stents available and approved for treatment of the aortoiliac segments, but essential features should be considered:
  - Trackability
  - Radial strength
  - Conformability
  - Stent retention
- Reliability and long-term results should guide practice patterns